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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/523,100 | 01/31/2005 | John W. Adams | 27.US2.PCT | 4553 |
| 27737 | 7590 | 03/27/2006 | EXAMINER | |
| ARENA PHARMACEUTICALS, INC. 6166 NANCY RIDGE DRIVE SAN DIEGO, CA 92121 | | | LI, RUIXIANG | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1646 | |

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/523,100

Applicant(s)

ADAMS ET AL.

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 85-121 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> . |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 85-96, drawn to a method of identifying a modulator of a RUP41 GPCR.

II. Claim 97, drawn to a process for making a modulator of a RUP41 GPCR.

III. Claims 98-100 and 104, drawn to a modulator.

IV. Claims 101 and 102, drawn to a method of modulating the activity of a RUP41 GPCR.

V. Claim 103, drawn to a method of preparing a composition.

VI. Claims 105-109, drawn to a method of cardioprotection.

VII. Claim 110, drawn to a method of making a knockout mouse or rat.

VIII. Claims 111 and 112, drawn to a method of using the knockout mouse or rat.

IX. Claims 113-115, drawn to an isolated rat RUP41 polynucleotide, a vector, and a host cell.

X. Claim 116, drawn to a GPCR fusion protein comprising a RUP41 amino acid sequence.

XI. Claim 117, drawn to a method of identifying a ligand of a RUP41 GPCR.

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XII. Claims 118 and 119, drawn to a method of radioimaging.

XIII. Claim 120, drawn to a non-human mammal transgenic for a human RUP41 GPCR.

XIV. Claim 121, a method of using the transgenic non-human mammal.

2. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-XIV appears to be the polypeptide of a RUP41 GPCR. However, Behan et al. (U. S. Patent No. 6555339, 102(e) date: 10/13/1998) teach an isolated polypeptide that is 100% identical to the amino acid sequence of SEQ ID NO: 2 of the present invention (see attached sequence alignment).

Therefore, the technical feature linking the inventions of Groups I-XIV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

3. The special technical features in Groups I-V are a method of identifying a modulator of a RUP41 GPCR, a process for making a modulator of a RUP41 GPCR, a modulator, a method of modulating the activity of a RUP41 GPCR, and a method of preparing a composition, respectively; the special technical features in Groups VI-X are a method of cardioprotection, a method of making a knockout mouse or rat, a method of using the knockout mouse or rat, an isolated rat RUP41 polynucleotide, a vector, and a host cell, and a GPCR fusion protein comprising a RUP41 amino acid

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sequence, respectively; whereas the special technical features in Groups XI-XIV are a method of identifying a ligand of a RUP41 GPCR, a method of radioimaging, a non-human mammal transgenic for a human RUP41 GPCR, and a method of using the transgenic non-human mammal, respectively.

4. Accordingly, Groups I-XIV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.
5. Furthermore, this application contains claims directed to the numerous amino acid/nucleic acid sequences, as listed in claims 85, 86, 88, 101, 116, 117, and 120. Each amino acid/nucleic acid sequence represents an *additional* invention group. As noted above, Behan et al. (U. S. Patent No. 6555339, 102(e) date: 10/13/1998) teach an isolated polypeptide that is 100% identical to the amino acid sequence of SEQ ID NO: 2 of the present invention (see attached sequence alignment). Therefore, the technical feature linking these RUP41 GPCR polypeptides does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Applicant is advised that a reply to this requirement must include an identification of an amino acid/ nucleic acid sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. The

Examiner notes that this is not a species election requirement; rather it sets forth additional invention groups.

Species Election

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: numerous diseases as listed in claims 89-91 and 106-108.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features because all the species do not appear to share a common pathological feature.

Should applicants elect Inventions comprising these claims, Applicants are further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02 (a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (I).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00

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pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.
Primary Examiner
March 18, 2006

Db 361 IFHPLIYAFTRQKFOVKLSKKKKRVSVIVEADPLPNNAVIHNSWIDPKRNKKTTFEEDSE 420
Qy 421 IREKRLVPOVYTD 433
Db 421 IREKRLVPOVYTD 433

RESULT 2

US-09-170-496D-190
Sequence 190, Application US/09170496D
Patent No. 6555339
GENERAL INFORMATION:
APPLICANT: Behan, Dominic P.
APPLICANT: Chalmers, Derek T.
APPLICANT: Liaw, Chen W.
TITLE OF INVENTION: No. 6555339-Endogenous, Constitutively Activated Human G Protein-
TITLE OF INVENTION: Receptors
FILE REFERENCE: ARN-0040
CURRENT APPLICATION NUMBER: US/09/170,496D
NUMBER OF SEQ ID NOS: 294
SOFTWARE: Patent in version 3.1
SEQ ID NO 190
LENGTH: 433
TYPE: PRT
ORGANISM: Homo sapiens
US-09-170-496D-190

Query Match 99.6%; Score 2183; DB 2; Length 433;
Best Local Similarity 99.6%; Pred. No. 1.5e-178;
Matches 429; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 1 MCFSPILKINMOSESNTITVDDIDIDINTNMVOPLSFQVSLTGFMLRIYVLGSLNL 60
Db 1 MCFSPILKINMOSESNTITVDDIDIDINTNMVOPLSFQVSLTGFMLRIYVLGSLNL 60
Qy 61 TVLVLYCKMSNLINSVSNITTMNLHVLVDIICVGCIPLTIVILLLSLSNTALICCFHFA 120
Db 61 TVLVLYCKMSNLINSVSNITTMNLHVLVDIICVGCIPLTIVILLLSLSNTALICCFHFA 120
Qy 121 CVSPASVSTAINVFATITDRDISVKNRANILTMGRVLMISIMIFSPFSLPIEYV 180
Db 121 CVSPASVSTAINVFATITDRDISVKNRANILTMGRVLMISIMIFSPFSLPIEYV 180
Qy 121 CUSPASVSTAINVFATITDRDISVKNRANILTMGRVLMISIMIFSPFSLPIEYV 180
Db 121 CUSPASVSTAINVFATITDRDISVKNRANILTMGRVLMISIMIFSPFSLPIEYV 180
Qy 181 FFSLOSAGTWENTKLLCVSTNEYTELGMYYHLVQIPIFFTVVVMILITTKILOALNI 240
Db 181 FFSLOSAGTWENTKLLCVSTNEYTELGMYYHLVQIPIFFTVVVMILITTKILOALNI 240
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Db 241 RIGTRFSTGQKKAKKKKTTISLTTOHEATDMSOSSGGRNVPGRVTSVVIILRAVYR 300
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Db 361 IFHPLIYAFTRQKFOVKLSKKKKRVSVIVEADPLPNNAVIHNSWIDPKRNKKTTFEEDSE 420
Qy 421 IREKRLVPOVYTD 433
Db 421 IREKRLVPOVYTD 433

RESULT 3

US-08-919-624-1
Sequence 1, Application US/08919624
Patent No. 5994097
GENERAL INFORMATION:
APPLICANT: Lal, Preeti
APPLICANT: Shah, Puri

APPLICANT: Guegler, Karl J.
APPLICANT: Corley, Neil C.
TITLE OF INVENTION: NEW HUMAN G-PROTEIN COUPLED
TITLE OF INVENTION: RECEPTOR
NUMBER OF SEQUENCES: 4
CORRESPONDENCE ADDRESS:
ADDRESSEE: Incyte Pharmaceuticals, Inc.
STREET: 3174 Porter Dr.
CITY: Palo Alto
STATE: CA
COUNTRY: USA
ZIP: 94304
COMPUTER READABLE FORM:
MEDIUM TYPE: Diskette
OPERATING SYSTEM: DOS
SOFTWARE: FASTSEQ for Windows Version 2.0
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/08/919,624
FILING DATE: Filed Herewith
PRIOR APPLICATION DATA:
APPLICATION NUMBER:
FILING DATE:
ATTORNEY/AGENT INFORMATION:
NAME: Billings, Lucy J.
REGISTRATION NUMBER: 36,749
TELEPHONE: 415-855-0555
TELEFAX: 415-845-4166
INFORMATION FOR SEQ ID NO: 1:
SEQUENCE CHARACTERISTICS:
LENGTH: 433 amino acids
TYPE: amino acid
STRANDEDNESS: single
TOPOLOGY: linear
IMMEDIATE SOURCE:
LIBRARY: CARDNOT01
CLONE: 282414
US-08-919-624-1

Query Match 98.9%; Score 2168; DB 1; Length 433;
Best Local Similarity 99.1%; Pred. No. 2.9e-177;
Matches 429; Conservative 0; Mismatches 4; Indels 0; Gaps 0;

Qy 1 MCFSPILKINMOSESNTITVDDIDIDINTNMVOPLSFQVSLTGFMLRIYVLGSLNL 60
Db 1 MCFSPILKINMOSESNTITVDDIDIDINTNMVOPLSFQVSLTGFMLRIYVLGSLNL 60
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Db 61 TVLVLYCKMSNLINSVSNITTMNLHVLVDIICVGCIPLTIVILLLSLSNTALICCFHFA 120
Qy 121 CVSPASVSTAINVFATITDRDISVKNRANILTMGRVLMISIMIFSPFSLPIEYV 180
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Db 181 FFSLOSAGTWENTKLLCVSTNEYTELGMYYHLVQIPIFFTVVVMILITTKILOALNI 240
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Db 241 RIGTRFSTGQKKAKKKKTTISLTTOHEATDMSOSSGGRNVPGRVTSVVIILRAVYR 300
Qy 241 RIGTRFSTGQKKAKKKKTTISLTTOHEATDMSOSSGGRNVPGRVTSVVIILRAVYR 300
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Db 301 HRRERROKRVFMSLLIISTFLCMTPISVLNTTILCLGSPDLVYKRLCFVMAVYGT 360
Qy 361 IFHPLIYAFTRQKFOVKLSKKKKRVSVIVEADPLPNNAVIHNSWIDPKRNKKTTFEEDSE 420
Db 361 IFHPLIYAFTRQKFOVKLSKKKKRVSVIVEADPLPNNAVIHNSWIDPKRNKKTTFEEDSE 420